DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

June 23, 2015

[redacted]

RE: Importation of Sodium Thiopental

Dear [redacted],

I would like to thank you for the information you provided in the conversation yesterday with Domenic Veneziano and myself regarding the potential importation of sodium thiopental into the United States. You told us that you represented several state governments seeking to import sodium thiopental as well as serving as the U.S. agent of [redacted], the manufacturer of a sodium thiopental product. You informed us that you and your clients believe that sodium thiopental can be legally imported into the United States despite the lack of FDA approval for such a product and previous court decisions. You asked about the possibility of the product proceeding to destination under bond prior to disposition. We cannot give you any assurance that the product will proceed to destination under bond. You further stated that if the products are released under bond, your clients would not make use of sodium thiopental unless and until such products are admitted into the United States. You also noted that you do not represent the State of Nebraska.

As I mentioned to you, should this product be offered for entry, FDA would conduct its review and, if detained, it would go through the normal detention and hearing process. I request that you provide advance notification to FDA of any upcoming sodium thiopental shipments to ensure such shipments are properly reviewed for admissibility into the United States. I would also ask that you provide us with a complete list of the parties you represent related to the potential importation of this product.

I would also like to reiterate that the United States District Court for the District of Columbia permanently enjoined FDA from permitting the entry of, or releasing any future shipments of, foreign manufactured sodium thiopental that appears to be misbranded or an unapproved

new drug in violation of 21 U.S.C. § 355. As we have explained, there is no FDA approved application for sodium thiopental.

Sincerely,

Douglas Stearn
Director
Office of Enforcement and Import Operations
U.S. Food and Drug Administration
Telephone: (301) 796-3668

REFERENCE 7

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Southwest Imports District
4040 N. Central Expy., Suite 300
Dallas, TX 75204

April 15, 2016

VIA ELECTRONIC MAIL

[redacted]

Re: Entry No. [redacted]/Thiopental Sodium[1]
imported by the [redacted]

Dear [redacted]:

On July 24, 2015, the [redacted] offered for import 1,000 one-gram vials of a product labeled as [redacted] (Thiopental Sodium USP). This entry was assigned Entry Number [redacted]

As detailed below, although we have not yet reached a final decision on the admissibility of this entry, we have tentatively determined that the thiopental sodium in Entry No. [redacted] appears to be in violation of 21 U.S.C. § 355(a) and appears to be misbranded under 21 U.S.C. § 352(f)(1) & (2). The thiopental sodium is a "drug" within the meaning of 21 U.S.C. § 321(g)(1)(C) because it is intended to affect the structure or function of the body. The thiopental sodium appears to violate 21 U.S.C. § 355 because it appears to be a "new drug" within the meaning of 21 U.S.C. § 321(p), it is not the subject of an approved application under 21 U.S.C. § 355(b) or (j), [redacted] In addition, the thiopental sodium appears to be misbranded under 21 U.S.C. § 352(f)(1), because its labeling appears to lack adequate directions for use, and it does not appear to be exempt from that requirement under the law enforcement exemption in 21 C.F.R. § 201.125. The thiopental sodium also appears to be misbranded under 21 U.S.C. § 352(f)(2), because its labeling appears to lack adequate warnings.

As discussed below, we are providing you with the opportunity to respond to these tentative conclusions before reaching a final determination on the status of the detained product.

[1] Thiopental sodium is also known as thiopental, thiopentone, sodium thiopental, and sodium pentothal.

[redacted]
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We are thus providing you a period of time when you can submit further information, whether in writing or in person, relevant to the admissibility of the entry. We will consider any additional information you provide in reaching a final conclusion regarding the admissibility of the product.

This letter specifies the bases upon which we have tentatively determined that the thiopental sodium appears to be in violation of the Federal Food, Drug, and Cosmetic Act ("FD&C Act"), 21 U.S.C. §§ 352(f)(1), 352(f)(2) & 355, and, therefore, subject to refusal of admission. This letter also explains the relevance of a recent court order to this shipment.

I. Background

A. Statutory Framework

Under the FD&C Act, the Secretary of Health and Human Services may request "samples of food, drugs, devices, tobacco products, and cosmetics which are being imported or offered for import into the United States . . . ." 21 U.S.C. § 381(a). The FD&C Act further provides that "[i]f it *appears* from the examination of such samples or otherwise that . . . (3) such article is adulterated, misbranded, or in violation of [21 U.S.C. § 355], . . . then such article shall be refused admission, except as provided in" 21 U.S.C. § 381(b). 21 U.S.C. § 381(a)(3) (emphasis added).

The FD&C Act thus does not require FDA to find that an article that is offered for importation is *actually* adulterated, misbranded, or in violation of 21 U.S.C. § 355 in order to refuse admission to that article; rather, the Agency has "broad authority to prohibit import" of any article that "*appears*" to violate the FD&C Act. *Continental Seafoods, Inc. v. Schweiker*, 674 F.2d 38, 43 (D.C. Cir. 1982) (emphasis added); *see Goodwin v. United States*, 371 F. Supp. 433,436 (S.D. Cal. 1972); *see also United States v. Food, 2998 Cases*, 64 F.3d 984, 992 (5th Cir. 1995) (FDA "can pursue the administrative procedures of § 381 and simply require reexportation of the goods," even where "the government lacks the ability to prove a violation of the [FD&C Act] by a preponderance of the evidence."); *Sugarman v. Forbragd*, 267 F. Supp. 817, 824 (N.D. Cal. 1967), *aff'd*, 405 F.2d 1189 (9th Cir. 1968); *K&K Merch. Group, Inc. v. Shalala*, No. 95Civl0082, 1996 U.S. Dist. LEXIS 4880, *22-23 (S.D.N.Y. 1996) (noting "the wide discretionary power FDA enjoys to determine the factors regarding its decision to grant or refuse admission of imported goods"). If an article is refused admission, it must be exported or destroyed within ninety days. 21 U.S.C. § 381(a).

B. The Proceedings

As noted, on or about July 24, 2015, [redacted] offered for import 1,000 one-gram vials of a product labeled as [redacted] (Thiopental Sodium USP). On August 5, 2015, U.S. Customs and Border Protection (CBP) detained this shipment of thiopental sodium. Ref. 1, Ex. 10 at 1. On August 18, 2015, you, as counsel for [redacted] requested that FDA instruct CBP to lift the detention and let the product proceed to destination. Ref. 1, Ex. 11 at 1-2. By letter dated August 24, 2015, FDA denied that request. Ref. 1, Ex. 12.

On August 24, 2015, FDA issued a "Notice of FDA Action" explaining that Entry [redacted] was detained and subject to refusal of admission based on the following: the product appeared to be misbranded under 21 U.S.C. § 352(f)(1) because its labeling appeared to lack adequate directions for use; the product appeared to be misbranded under 21 U.S.C. § 352(f)(2) because its labeling appeared to lack adequate warning against use in a pathological condition or by children where it may be dangerous to health or against an unsafe dose, method, administering duration, application, in manner/form, to protect users; and the product appeared to be a new drug that lacked an approved new drug application as required by 21 U.S.C. § 355. Ref. 1, Ex. 1 at 1-2. The notice, which was sent to [redacted] as the listed consignee of the entry, specified that testimony regarding the admissibility of the entry must be submitted to FDA by September 14, 2015. Ref. 1 Ex. 1 at 2.

On September 10, 2015, as counsel for [redacted] you requested an extension to respond to the Notice of FDA Action. On the same day, FDA granted an extension until October 23, 2015. *See* Ref. 1, Ex. 1 at 3.

On October 23, 2015, on behalf of [redacted] you submitted written testimony regarding the detained product. Ref. 1. Your letter provided information regarding why you believe the product should not be refused admission, and you requested an in-person hearing with appropriate FDA personnel. Ref. 1 at 1. In submitting the written testimony, you also requested that FDA transfer the matter to the Director, Office of Enforcement and Import Operations ("OEIO") or his designee, who would serve as the hearing officer for this detention. In a telephone discussion on December 10, 2015, FDA counsel informed you that the Agency intended to follow its typical practice of having staff in the District Office determine admissibility, rather than transferring the matter to OEIO. In a subsequent telephone discussion with FDA counsel on February 2, 2016, FDA asked whether [redacted] still wanted to present information regarding the detained product in person. Subsequently, in a series of phone communications on March 11, 2016, you stated that [redacted] concurred with an approach in which FDA would send a written, tentative decision to you and provide ADC with the opportunity to respond before reaching a final decision.

[redacted]
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Our tentative conclusion that the thiopental sodium appears to violate 21 U.S.C. §§ 352(f)(1), 352(f)(2), and 355 is based on a review of the entire record in this matter, including the label, labeling, and packaging for the thiopental sodium and the information you submitted on October 23, 2015.

C. The Detained Product

Entry No. [redacted] consists of 1,000 one-gram vials of [redacted] (Thiopental Sodium USP). Ref. 2 at 2. The labels on the vials of thiopental sodium state:

1 gm
[redacted]
Thiopental Sodium USP
Sterile

Rx Only CIII
[redacted]
manufacturer and distribution services
For law enforcement purpose only.

Made in [redacted]
Code No: [redacted]
Batch No.: [redacted]
Mfg. Date: 06/2015
Exp. Date: 05/2017

Marketed by:
[redacted]

Ref. 3 at 23-24. The label bears no other information. Ref. 3 at 23-24; Ref. 1, Ex. 3 at 1. *See also* Ref. 1 at 2 ("Aside from the information printed on the label . . ., there is no additional labeling information accompanying the drug specifying information about its properties or uses."). The sticker on the outside of a box of vials repeats the information on the vial label. Ref. 3 at 43. The boxes contain no package inserts, leaflets, or other materials with directions for use or warnings about the use of the thiopental sodium. An outside box label lists the [redacted] as the consignee. Ref. 3 at 26-27. In addition to the label listing

"[redacted] manufacturer and distribution services," the certificate of analysis in the entry documentation for the thiopental sodium states that it is "[m]anufactured by" "[redacted]" Ref. 2 at 4.

Thiopental sodium is a barbiturate that depresses nervous system function to render a man or woman unconscious, Ref. 1, Ex. 13 at 3-5 (Goodman and Gilman's, The Pharmacological Basis of Therapeutics, 11th ed., p. 347-349), which can cause death in a large enough dose. Ref. 1, Ex. 16 at 10 (History of Barbiturates, p. 338). As classified among anesthetics, it is an ultrashort-acting agent. Ref. 1, Ex. 16 at 10 (History of Barbiturates, p. 338). Like other anesthetics, its effects vary based on patient-specific factors such as weight and age, and its use must be calibrated. Ref. 1, Ex. 15 at 3-5 (Goodman and Gilman's, p. 347-349). In addition, thiopental sodium can produce allergic reactions in some individuals. Ref. 1, Ex. 15 at 6 (Goodman and Gilman's, p. 350). It is a schedule III controlled substance. Ref. 1 at 2; Ref. 1 Ex. 3.

There are currently no FDA-approved applications in effect for the thiopental sodium. [redacted]

D. <u>The District Court's Order</u>

For decades, FDA generally exercised enforcement discretion regarding thiopental sodium used for capital punishment purposes. *See Heckler v. Chaney*, 470 U.S. 821, 835-36 (1985). *See also* Ref. 1, Ex. 14 at 1-2 (2010 FDA statement explaining that FDA was exercising enforcement discretion and choosing to continue to defer to law enforcement as a policy matter). In February 2011, a group of prisoners on death row in Arizona, California, and Tennessee filed suit challenging FDA's release of imported thiopental sodium for use as an anesthetic as part of lethal injection. In March 2012, the U.S. District Court for the District of Columbia granted the plaintiffs' motion for summary judgment. *See Beaty v. FDA*, 853 F. Supp. 2d 30 (D.D.C. 2012), *aff'd in part, rev'd in part sub nom. Cook v. FDA*, 733 F.3d 1 (D.C. Cir. 2013). The District Court's March 2012 Order, as modified in June 2012, permanently enjoins FDA from "permitting the entry of, or releasing any future shipments of, foreign manufactured thiopental that appears to be misbranded or in violation of 21 U.S.C. [§] 355 [as an unapproved new drug]." Ref. 4 at 1-2; Ref. 5 at 2.

On June 23, 2015, FDA sent you a letter after telephone discussions regarding the potential importation of thiopental sodium into the United States. Ref. 6. The letter explained that you told FDA that you represented several state governments seeking to import thiopental sodium and were also serving as the U.S. agent of [redacted], the manufacturer of a thiopental sodium product. Ref. 6 at 1. Among other things, FDA's letter reiterated that the

District Court permanently enjoined FDA from permitting the entry of, or releasing any future shipments of, foreign-manufactured thiopental sodium that appears to be misbranded or an unapproved new drug. Ref. 6 at 1. The letter also reiterated that there was no FDA-approved application for thiopental sodium. Ref. 6 at 2.

II. The Detained Thiopental Sodium Appears To Be An Unapproved New Drug

[redacted] acknowledges that the thiopental sodium is a drug, because it is intended to affect the structure and function of the body. Ref. 1 at 5 (discussing 21 U.S.C. § 321(g)(1)(C) and stating that "[t]his second definition applies here"). [redacted] also admits that its purpose for obtaining the detained thiopental sodium is to "utilize thiopental sodium in executions." Ref. 1, Ex. 13 ¶ 5. Nevertheless, as set forth in your October 23 letter, [redacted] argues that the thiopental sodium "does not fit within the statutory definition of a 'new drug,'" because its labeling "does not prescribe, recommend, or suggest any conditions of use." Ref. 1 at 7. In particular, [redacted] asserts that "[w]hen no conditions of use are so specified, it is not possible for FDA to establish that a drug is a 'new drug.'" Ref. 1 at 7. [redacted] concludes that it is therefore legal to distribute the drug even in the absence of an approved NDA or ANDA. Ref. 1 at 7.

For the reasons discussed below, we believe the detained thiopental sodium's labeling does "suggest[]" conditions of use. *See* 21 U.S.C. § 321(p)(1) (defining "new drug"). Those conditions of use are as part of a lethal injection. It appears the drug is not generally recognized as safe and effective under those conditions of use, or under any other conditions of use. Therefore, we tentatively conclude that it appears to be an unapproved new drug.

A. The Detained Thiopental Sodium's Labeling Suggests the Conditions Under Which It Will Be Used: For Lethal Injection

As discussed, [redacted] does not dispute that the detained thiopental sodium is a drug. If a product is a drug, then, as a matter of law, it is a "new drug" unless it is generally recognized among qualified experts as being "safe and effective under the conditions prescribed, recommended, or suggested in its labeling." 21 U.S.C. § 321(p)(1).

The labeling of the detained thiopental sodium suggests the conditions under which it will be used: as a lethal injection drug.[2] The label states "Thiopental Sodium USP," "Sterile," "Rx only," and "[f]or law enforcement purpose only." Ref. 3 at 23-24; Ref. 1, Ex. 3 at 1. In addition, an outside box label lists the [redacted] as the consignee.

[2] The labeling of a drug includes its container label. 21 U.S.C. § 321(m).

Ref. 3 at 26-27.[3] Those elements alone suggest the drug's use. Moreover, thiopental sodium is a well-known death penalty drug used for anesthesia in multi-drug protocols or, sometimes, as the lethal agent itself. *See, e.g.*, *Baze v. Rees*, 553 U.S. 35, 44 (2008); Death Penalty Information Center, State by State Lethal Injection, DEATHPENALTYINFO.ORG, http://www.deathpenaltyinfo.org/state-lethal-injection (last visited Apr. 10, 2016) (describing states' use of thiopental sodium in both three-drug and single-drug protocols); Emma Marris, Death-row drug dilemma, NATURE (27 Jan. 2011), http://www.nature.com/news/2011/110121/full/news.2011.53.html. [redacted] notes that "[t]he standard reference source for pharmacology indicates that thiopental sodium is a barbiturate that produces unconsciousness and anesthesia." Ref. 1 at 4 n.2. [redacted] states further that "[t]his effect is well known; the drug has been used for purposes of anesthesia since before the [FD&C Act] was enacted in 1938." Ref. 1 at 4 n.2.

The use suggested by the information in the drug's labeling is confirmed by [redacted] submission. For example, the declaration [redacted] submitted as Exhibit 13 states:

> [redacted] has purchased the thiopental sodium currently being detained by the FDA. [redacted] *has previously purchased and used thiopental sodium in numerous executions before it became commercially unavailable to correctional facilities for such purpose.* In order to resume use of thiopental sodium for executions, no legislative or regulatory action is necessary. My responsibilities to determine the lethal injection procedure include the discretionary decision to determine which substance or substances to use. As part of my statutory duty to ensure that lawful capital sentences are carried out via lethal injection, *I am attempting to once again utilize thiopental sodium in executions and will do so when necessary if the FDA releases its hold on the purchased thiopental sodium*.

Ref. 1 at Ex. 13 ¶ 5 (emphasis added). The October 23 letter underscores the point, stating that "the specific law enforcement purpose [of the thiopental sodium] is to effectuate lawfully-imposed capital sentences through lethal injection." Ref. 1 at 4.[4]

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[3] The consignee field in the import entry forms confirms that the shipment is destined for [redacted] Ref. 2 at 1.

[4] We note that the execution procedures that you submitted on October 23, 2015 do not describe [redacted] execution procedure with respect to thiopental sodium. Ref. 1, Ex. 13, Ex. A. Instead, those procedures, dated July 2012, describe [redacted] use of pentobarbital. Ref. 1, Ex. 13, Ex. A at 8-10. We understand that the thiopental sodium would be used either as the anesthetic in a multi-drug protocol, as Texas has used it in the past, *see, e.g.*, Jennifer Horne, Lethal Injection Drug Shortage, COUNCIL OF STATE GOVERNMENTS E-NEWSLETTER (Feb. 17, 2011), http://www.csg.org/pubs/capitolideas/enews/issue65_4.aspx (discussing thiopental sodium as "an anesthetic that is part of the three-drug cocktail used in lethal injections" and stating that Texas had enough of the drug to execute two death-row inmates), or in a single-drug protocol,

In sum, the labeling of the thiopental sodium plainly suggests the conditions under which the drug will be used.[5] The conditions suggested in the labeling are to affect nervous system function of an inmate as part of an execution.

B. The Detained Thiopental Sodium Is Not Generally Recognized As Safe and Effective for Any Use

As discussed, if a product is a drug, then, as a matter of law, it is a "new drug" that must be approved by FDA before it can be lawfully distributed in interstate commerce, unless its composition is such that it is generally recognized among qualified experts as being "safe and effective under the conditions prescribed, recommended, or suggested in its labeling." 21 U.S.C. §§ 321(p)(1), 331(d), 355. General recognition of a drug as safe and effective must rest on a consensus among qualified experts based on adequate and well-controlled clinical trials that are published in the scientific and medical literature. *See, e.g.*, *Weinberger v. Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 629 (1973); *Weinberger v. Bentex Pharm., Inc.*, 412 U.S. 645, 652 (1973); *United States v. Article of Drug . . . 4,680 Pails*, 725 F.2d 976, 987 (5th Cir. 1984); *United States v. Undetermined Quantities . . . Equidantin*, 675 F.2d 994, 1000-01 (8th Cir. 1982); *Premo Pharm. Labs., Inc. v. United States*, 629 F.2d 795, 803-04 (2d Cir. 1980)

Here, the "conditions . . . suggested in the labeling" of the detained thiopental sodium are use as part of a lethal injection. Under those conditions, we have tentatively determined that it appears that the drug is not generally recognized as safe and effective. For example, there are no adequate and well-controlled trials evaluating [redacted] thiopental sodium for use as part of a lethal injection that have been published in the scientific literature. Thus, it appears the detained thiopental sodium is not generally recognized as safe and effective for use in lethal injection. *See Tri-Bio Labs., Inc. v. United States*, 836 F.2d 135, 141 (3d Cir. 1987) ("[E]ither the unawareness of the drug product by experts generally or a genuine dispute among qualified experts regarding a drug product's safety and effectiveness preclude[s] its qualifying for exclusion as 'generally recognized.'") (internal quotation omitted).

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as utilized in other states. *See, e.g.*, Jennifer Sullivan, Killer on death row 16½ years is executed, THE SEATTLE TIMES (Sept. 10, 2010) (describing a 2010 Washington execution using thiopental sodium alone).

[5] You argue that the thiopental sodium is analogous to prescription chemicals used in pharmacy compounding, which must bear a legend, and which, you argue, "d[o] not meet the statutory definition of 'new drug,' because [the chemicals'] labeling does not specify *any* conditions of use." Ref. 1 at 7-8. (emphasis in original). This comparison is inapt because, among other things, it ignores the fact that the detained thiopental sodium has conditions for use suggested in its labeling. Moreover, as discussed in Section I.A., a product is subject to refusal of admission if it *appears* to be a new drug that is not approved in violation of 21 U.S.C. § 355.

[redacted] argues that "[w]hen no conditions of use are . . . specified" in the labeling, "it is not possible for FDA to establish that a drug is a 'new drug.'" Ref. 1 at 7. This argument is beside the point because, as discussed above, we tentatively conclude that there are conditions for use suggested in the labeling for the detained product. In any event, this argument is not persuasive. There are no adequate and well-controlled trials published in the scientific literature that evaluate [redacted] thiopental sodium for any use, and therefore [redacted] thiopental sodium cannot qualify as generally recognized as safe and effective *for any use*.

Moreover, the detained thiopental sodium is not the subject of an approved new drug application, an approved abbreviated new drug application [redacted] we tentatively conclude that it appears to be an unapproved new drug.

III. The Detained Thiopental Sodium Appears to Be Misbranded Under 21 U.S.C. § 352(f)(1)

We tentatively conclude that, in addition to appearing to be an unapproved new drug, the thiopental sodium appears to be misbranded because its labeling does not bear adequate directions for use.

The thiopental sodium that [redacted] is attempting to import includes no directions for those who would administer the drug or receive it. It lists no recommended dose, and it includes no instructions for reconstituting the powder inside the vials. It includes no precautions, contraindications, or warnings, or other information required in prescribing information for health professionals. Instead, it bears little text beyond "[f]or law enforcement purpose only," "Rx only," "CIII," "1 gm," and manufacturer information. That text provides inadequate directions for a prescription-drug barbiturate that will be administered to humans to produce anesthesia as part of a lethal injection procedure, or, possibly, to be used as the sole drug for lethal injection.

[redacted] argues that the thiopental sodium is exempt from the statutory requirement to bear adequate directions for use under 21 C.F.R. § 201.125, entitled "Drugs for use in teaching, law enforcement, research, and analysis." Ref. 1 at 3. However, the law enforcement exemption within 21 C.F.R. § 201.125 does not apply here, for the reasons discussed below.

A. The Detained Thiopental Sodium's Labeling Does Not Bear Adequate Directions for Use

Under section 502(f)(1) of the FD&C Act, 21 U.S.C. § 352(f)(1), a drug is deemed to be misbranded unless its labeling bears adequate directions for its use. "Adequate directions for use" means "directions under which the layman can use a drug safely and for the purposes for which it is intended." 21 C.F.R. § 201.5; *United States v. Articles of Drug (Rucker Pharmacal)*, 625 F.2d 665, 671-75 (5th Cir. 1980).

The detained thiopental sodium is a prescription drug, as reflected by the "Rx Only" on its label. Ref. 1, Ex. 3 at 1. [redacted] recognizes in its October 23 letter that the detained product merits the classification: "[t]he drug easily satisfies the definition of a prescription drug; it is hard to imagine FDA suggesting that a drug that produces unconsciousness and anesthesia is a non-prescription drug." Ref. 1 at 4 n.2.[6]

A prescription drug is, by definition, "not safe for use except under the supervision of a practitioner licensed by law to administer such drug." 21 U.S.C. § 353(b)(1)(A). As a result, it is impossible to provide "adequate directions for [lay] use" for prescription drugs, and they are "presumptively misbranded." *United States v. Regenerative Scis., LLC*, 741 F.3d 1314, 1324 (D.C. Cir. 2014). To avoid being misbranded, a prescription drug must qualify for an exemption from the adequate directions for use requirement. *Rucker Pharmacal*, 625 F.2d at 673.

One such exemption is the exemption in 21 C.F.R. § 201.100, for prescription drugs for human use. To qualify for that exemption, if the prescription drug is a new drug, it must bear the "labeling authorized by the approved new drug application . . . ." 21 C.F.R. § 201.100(c)(2). Because the detained thiopental sodium is an unapproved new drug, for the reasons discussed above, we tentatively conclude that it cannot qualify for the exemption in section 201.100.

Even if the detained product were not an unapproved new drug, it does not bear the label or labeling required to qualify for the exemption in section 201.100. As a starting point, the label of a prescription drug must provide the recommended or usual dosage and the route of administration (such as "intravenous bolus," "sublingual," or "parenteral"), under 21 C.F.R. §§ 201.100(b)(2) and (3), but here the label does not include that information. In addition, the labeling must include sufficient information to enable licensed practitioners to "use the drug safely and for the purposes for which it is intended," under 21 C.F.R. §§ 201.100(c)(1) and (d)(1). Thus, the labeling must include a package insert with comprehensive information for

[6] Indeed, a previous thiopental sodium product for injection, marketed through January 2011, was a prescription drug.

health professionals in enumerated categories. 21 C.F.R. § 201.100(d)(3) (referencing the requirements of §§ 201.56 and 201.57 for newer-format prescription drug labeling and § 201.80 for older-format labeling). These categories range from "Indications and Usage," 21 C.F.R. §§ 201.56(d)(1), 201.80(c), and "Dosage and Administration," 21 C.F.R. §§ 201.56(d)(1), 201.80(j), to "Precautions," which can address "any special care to be exercised by the practitioner for safe and effective use of the drug." 21 C.F.R. §§ 201.57(c)(6)(ii), 201.80(f).

Here, we tentatively conclude that the thiopental sodium [redacted] seeks to import appears to bear inadequate labeling. The package includes no prescribing information and thus lacks the detailed information required by law for health professionals (e.g. dosing information and precautions). *See* 21 C.F.R. §§ 201.100(c), 201.100(d), 201.56, 201.57, 201.80. Like other drugs that bear essentially no directions for use, the thiopental sodium appears to be misbranded. *See, e.g.*, *Colgrove v. United States*, 176 F.2d 614, 616 (9th Cir. 1949) (directions for use are inadequate if there is an omission of directions for use for all conditions for which a drug is recommended or suggested in advertising matter sponsored by the manufacturer or distributor).

In summary, we tentatively conclude that it appears the thiopental sodium fails to meet the labeling requirements for a prescription drug for human use, and thus it appears to be misbranded under 21 U.S.C. § 352(f)(1). The law enforcement exemption does not exempt the thiopental sodium shipments at issue here from the adequate directions for use requirement, for reasons discussed below.

B. FDA's Law Enforcement Exemption Does Not Extend to Drugs for Lethal Injection, but Instead Covers Investigative Purposes that Do Not Involve Clinical Use

[redacted] asserts that the detained thiopental sodium is not misbranded under 21 U.S.C. § 352(f)(1) because it "falls within the exemption established by 21 C.F.R. § 201.125," which "applies to a drug that is 'shipped or sold to, or in the possession of, persons . . . engaged in law enforcement, . . . and is to be used only for . . . law enforcement.'" Ref. 1 at 3. We do not dispute that use of a drug in lethal injection is use for a law enforcement purpose in one sense of that term. However, the text of 21 C.F.R. § 201.125, its history, and its regulatory framework demonstrate that FDA's law enforcement exemption does not extend to drugs for lethal injection. The regulation in full states that:

> A drug subject to § 201.100 or § 201.105, shall be exempt from section 502(f)(1) of the act if [1] *shipped or sold to, or in the possession of, persons* regularly and lawfully engaged in instruction in pharmacy, chemistry, or medicine not involving clinical use, or *engaged in law enforcement*, or in research not involving clinical

[redacted]

> use, or in chemical analysis, or physical testing, and [2] *is to be used only for* such instruction, *law enforcement*, research, analysis, or testing.

21 C.F.R. § 201.125 (emphases added).

When FDA promulgated the law enforcement exemption in 1956, no state utilized lethal injection. *Baze*, 553 U.S. at 42. At the time, the most common method of execution in the United States was the electric chair. *Id.* *See also* John West, *All the Ways America has Chosen to Execute People Since 1776*, Quartz (Feb. 22, 2015), http://qz.com/346332/all-the-ways-america-has-chosen-to-execute-people-since-1776/ (compiling data from the Death Penalty Information Center and the Inter-University Consortium for Political and Social Research). No state would employ lethal injection in an execution until 1982, in Texas. Deborah W. Denno, *Getting to Death: Are Executions Constitutional?*, 82 Iowa L. Rev. 319, 375 (1997). Thus, the regulation could not have been intended to apply to drugs for lethal injection.

When FDA promulgated the exemption, it did not give an extensive rationale. Instead, the Agency stated that its normal labeling requirements were unnecessary for the protection of the public health in the circumstances to which the exemption applied. More precisely, FDA's special Federal Register finding stated:

> Notice, and public procedure are not necessary prerequisites to the promulgation of this order . . . since [1] the exemption granted applies only to drugs and devices shipped, sold, or in the possession of persons engaged in law-enforcement and in such cases the labeling requirements are not necessary for the protection of the public health, [2] since the amendment relaxes existing requirements; and [3] since it would be against public interest to delay providing for the amendment.

Regulations for the Enforcement of the Federal Food, Drug, and Cosmetic Act; Exemption of Certain Drugs and Devices from Labeling Requirements, 21 Fed. Reg. 2309, 2327 (Apr. 11, 1956) (emphasis added) (final rule).

The preambles to 21 C.F.R. § 201.125 do not state the specific law enforcement uses that FDA envisioned exempting. *See* 21 Fed. Reg. 2327 (1956 special finding); 17 Fed. Reg. 6819-6820 (1952 final rule); Drugs and Devices: Directions for Use; Drugs for Prescription Dispensing, 17 Fed. Reg. 1079, 1130-1133 (1952) (proposed rule). However, FDA was intimately involved in the investigation of illegal distribution of narcotics, barbiturates, and amphetamines at the time the Agency promulgated the exemption. *See* Wallace F. Janssen, FDA Historian, *The Story of the Laws Behind the Labels*, http://www.fda.gov/AboutFDA/WhatWeDo/History/Overviews/ucm056044.htm (last accessed Jan. 26, 2016) (discussing undercover sales by FDA inspectors and the Agency's 1940's efforts to prosecute dealers of barbiturates and amphetamines sold without prescriptions, before the

[redacted]

creation of the Drug Enforcement Agency). In 1955, the Deputy Commissioner of Food and Drugs went before Congress to express concern over misuse of amphetamines and barbiturates and offer suggestions for additional federal regulation of production and distribution of the drugs. *Traffic In, and Control of, Narcotics, Barbiturates, and Amphetamines, Hearings Before the H. Subcomm. on Ways and Means*, 84th Congress 1119-1120, 1123 (1955) (statement of John L. Harvey, FDA Deputy Commissioner, Nov. 17, 1955). In his statement, the FDA Deputy Commissioner described himself as a "food and drug law enforcement officer" and discussed efforts by "State enforcement officers" who found themselves underequipped in terms of manpower and laws. *Id.* at 1120. Thus, investigative law enforcement actions related to prescription drugs were a focus of FDA and the public immediately before FDA promulgated the law enforcement exemption in section 201.125. *See id.* In short, the historical context of the exemption indicates that the law enforcement exemption encompasses law enforcement purposes related to investigative work, rather than drugs for lethal injection.

In greater detail, the law enforcement exemption can encompass law enforcement purposes like controlled buys and officer training. For example, a violative drug could be "sold to" an undercover agent "engaged in law enforcement" and "used only for . . . [the] law enforcement" purpose of proving the seller's illegal activity. *See* 21 C.F.R. § 201.125. Similarly, the law enforcement exemption could extend to uses like forensic testing. Alternatively, the exemption could facilitate instruction of officers on the look and feel of particular drug products. In all of these cases, adequate directions for use would be unnecessary for the protection of public health, because the drugs would not be intended for uses involving administration to humans.

Looking to the regulation as a whole, we tentatively conclude that section 201.125 exempts drugs from the requirement that their labeling bear adequate directions for use only where those drugs are not for clinical use. The regulation's seven categories are: (1) instruction in pharmacy not involving clinical use, (2) instruction in chemistry not involving clinical use, (3) instruction in medicine not involving clinical use, (4) law enforcement, (5) research not involving clinical use, (6) chemical analysis, and (7) physical testing. In this context, "clinical use" conveys uses involving administration of drugs to humans (or animals, for animal drugs). *See, e.g.*, 21 C.F.R. § 312.3 (defining "clinical investigation" to mean "any experiment in which a drug is administered or dispensed to, or used involving, one or more human subjects"). Where clinical use might be expected, such as with "instruction in medicine" or with "research," FDA explicitly stated that the exemption did not extend to those uses. 21 C.F.R. § 201.125. Although FDA did not attach the same modifier, "not involving clinical use," to "law enforcement," the agency very likely did not anticipate clinical use of drugs pursuant to this exemption. It took the same approach for chemical analysis and physical testing. If the "clinical use" limitation applied only to categories (1)-(3), and (5), the regulation would require substantive labeling for medical school professors administering drugs to humans, but not law enforcement personnel, which

[redacted]
April 15, 2016
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could not have been what FDA intended. Like "chemical analysis" and "physical testing," the "law enforcement" within section 201.125 does not encompass clinical uses involving administration of drugs to humans.

In fact, an earlier, 1952 version of what was then 21 C.F.R. § 1.106(m) included only the six categories from "instruction in pharmacy . . . not involving clinical use" to "physical testing," without "law enforcement." Regulations for the Enforcement of the Federal Food, Drug, and Cosmetic Act; Drugs and Devices; Directions For Use; Exemption From Prescription Requirements, 17 Fed. Reg. 6807, 6819-6820 (Jul. 25, 1952) (final rule). Thus, FDA specifically inserted the law enforcement exception into a regulation with six other categories of uses that do not involve administration of drugs to humans. *See id.*

In summary, we tentatively conclude that section 201.125 does not apply to the detained thiopental sodium for use in lethal injection. Because it appears its labeling fails to bear adequate directions for use and it is not exempt from that requirement, we tentatively conclude that the detained thiopental sodium appears to be misbranded under 21 U.S.C. § 352(f)(1).

IV. The Detained Thiopental Sodium Also Appears to Be Misbranded Because It Lacks Adequate Warnings

We tentatively conclude that the thiopental sodium also appears to be misbranded because its labeling fails to bear adequate warnings. *See* 21 U.S.C. § 352(f)(2). [redacted] argues that no warnings are necessary for the thiopental sodium, because the purpose of section 502(f)(2) of the FD&C Act is to provide warnings to lay patient users "as they take their own drugs" for medicinal purposes, and there are no patient "users" within the meaning of section 502(f)(2) here. Ref. 1 at 5. In the alternative, [redacted] argues that FDA has not established that the "law enforcement purpose only" legend is not an "adequate" warning under section 502(f)(2). Ref. 1 at 6. We disagree with both of these arguments.

A. Drugs Must Bear Necessary Warnings

Section 502(f)(2) of the FD&C Act, 21 U.S.C. § 352(f)(2), requires drug labeling to bear "such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users." [redacted] argues that "the purpose of section 502(f)(2) is to guide lay patient users as they take their own drugs." Ref. 1 at 5. However, FDA has required warnings clearly intended for medical professionals, in addition to laypeople, pursuant to section 502(f)(2) and its implementing regulations. *See, e.g.*, Requirements on Content and Format of Labeling for Human Prescription Drug and Biological

Products, 71 Fed. Reg. 3922, 3964 (final rule) (citing 502(f) and quoting the language of 502(f)(2) in the discussion of legal authority for the Physician Labeling Rule, which governs prescribing information for health professionals). Indeed, FDA regulations promulgated pursuant to sections 502(f)(1) and 502(f)(2) require detailed drug labeling *for health professionals* that features a full section of warnings and precautions, as well as sections for contraindications and adverse reactions. 21 C.F.R. §§ 201.56(d); 201.57(c)(6), (c)(5), (c)(7) (requirements for newer-format labeling). *See also* 21 C.F.R. § 201.80 (requirements for older-format labeling). These warnings serve a critical function. They inform medical professionals about specific possible risks in administering a drug, including the risk that a drug will be ineffective for its intended use.

In short, contrary to [redacted] assertion that section 502(f)(2) warnings are only necessary for circumstances involving lay patient users, Ref. 1 at 5, the requirements of 502(f)(2) are indeed relevant here.

B. "For Law Enforcement Purpose Only" Is Not An Adequate Warning

We disagree that "for law enforcement purpose only" is an adequate warning and, as discussed, tentatively conclude that the thiopental sodium appears to be misbranded because it appears that its labeling fails to bear adequate warnings. We recognize that [redacted] requested an opportunity to relabel the thiopental sodium to include the warnings FDA deems adequate. Ref. 1 at 6 n.3. It is [redacted] responsibility to include adequate warnings, and it is not FDA's role to specify in this context what warnings would suffice. Moreover, even if [redacted] addressed the lack of adequate warnings, if FDA determines that the detained product appears to be an unapproved new drug under section 505(a) or a misbranded drug under section 502(f)(1), the product would still be subject to refusal of admission.

V. Conclusion

For the reasons set forth above, we tentatively conclude that the thiopental sodium appears to be an unapproved new drug and misbranded. As discussed above, [redacted] initially requested a meeting with the Agency to discuss this import entry, but later agreed it would be more productive to first review the Agency's tentative conclusions. We are therefore providing you with the opportunity to respond to the tentative conclusions expressed herein, either in writing or in a meeting with the Agency. If you prefer a meeting, please contact us as soon as possible so that we can identify possible dates for the meeting. If you prefer to respond in writing, please respond to this letter within 20 calendar days of receipt. We will take any information you provide in response to this letter into account in reaching a final conclusion regarding the admissibility of this product. Please note that if FDA reaches a final conclusion

[redacted]
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that the detained product appears to be in violation of the FD&C Act for any of the reasons discussed in this letter, the Agency must refuse admission to the product pursuant to the orders issued in *Beaty*, 853 F. Supp. 2d 30, *aff'd in part, rev'd in part sub nom. Cook*, 733 F.3d 1.

Sincerely,

Rosa L. Santos
Compliance Officer
Dallas District Office

[redacted]
April 15, 2016
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References:

Reference 1: Release Request for Thiopental Sodium on Behalf of the [redacted], October 23, 2015

Exhibit 1: FDA Notices of Action

. . .

Exhibit 3: Thiopental Label

. . .

Exhibit 10: CBP Detention Notice

Exhibit 11: Request for Delivery of Imported Sodium Thiopental

Exhibit 12: FDA Response to Request for Delivery

Exhibit 13: Affidavit

Exhibit 14: FDA Statement regarding Sodium Thiopental

Exhibit 15: Excerpt from Goodman & Gilman's The Pharmacological Basis of Therapeutics

Exhibit 16: History of Barbiturates

. . .

Reference 2: Entry Documentation, [redacted]

Reference 3: Photos of Detained Thiopental Sodium

Reference 4: Beaty Cook Order, March 27, 2012

Reference 5: Beaty Cook Order, June 22, 2012, Modifying Order

Reference 6: FDA Letter on Sodium Thiopental Importation, June 23, 2015

REFERENCE 8

From: [redacted]
To: Santos, Rosa L
Cc: Veneziano, Domenic J.; Stearn, Douglas; [redacted]
Subject: Detained Thiopental Sodium/Entry No. [redacted]
Date: Friday, May 20, 2016 3:50:54 PM
Attachments: BLEA Response to April 15 Tentative Decision (TX TDCJ D97-0846119-6) 052016.pdf
Attachment A.PDF
Attachment B.PDF
Attachment C.PDF
Attachment D.PDF
Attachment E.PDF

Hello Ms. Santos

I am writing as counsel for the [redacted] providing the attached submission (with five attachments) in response to the Tentative Decision that you sent to me on April 15, 2016.

I would appreciate it if you would confirm receipt via return email.

Best regards

[redacted]

[redacted]

[redacted]

COMMERCIAL CONFIDENTIAL COMMUNICATION

May 20, 2016

***Via Electronic Mail*: rosa.santos@fda.hhs.gov**

Rosa L. Santos, Compliance Officer
U.S. Food and Drug Administration
4040 N. Central Expressway Suite 300
Dallas, TX 75204

Re: Release Request for Thiopental Sodium on Behalf of [redacted] – Entry No. [redacted]

Dear Ms. Santos:

We are making this submission, as counsel for the [redacted] in response to the April 15, 2016 Tentative Decision concerning the detained drugs identified above. We appreciate the opportunity to provide additional information before a final decision is made regarding admissibility of the detained drugs.[1] As explained below, we respectfully submit that all of the Tentative Decision's conclusions regarding the claimed violations of FFDCA sections 505, 502(f)(1) and 502(f)(2) (21 U.S.C. §§ 355, 352(f)(1) and 352(f)(2)) are incorrect. The Tentative Decision's conclusion that the detained drugs must be refused admission into domestic commerce under FFDCA section 801(a) (21 U.S.C. § 381(a)) also is incorrect.

In the interest of efficiency, we are objecting to the Tentative Decision's conclusions without restating all of the information and argument previously submitted to you on October 23, 2015 (which is incorporated herein by reference).[2] We hereby preserve all issues and arguments stated in our prior submission even if not restated here. Our failure to respond to a specific point in the

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[1] Based on the April 15, 2016 Tentative Decision we understand that the District Director has designated you as the official to act on his behalf in making the final decision whether the detained drugs are in compliance with the Federal Food, Drug, and Cosmetic Act (FFDCA) and the final decision whether to refuse the entry. 21 C.F.R. §§ 1.83(b), 1.94. Please advise us immediately if that is not correct.

[2] In the discussion below, citations to Attachments are to the documents that accompany this submission and citations to Exhibits are to those filed with our original October 23, 2015 submission, including our supplemental submission on May 13, 2016.

[redacted]

Tentative Decision is not a concession that the point is correct or a waiver of any objection to that point.[3]

I. The Detained Drugs Do Not Violate Statutory Requirements Governing Adequate Directions for Use

The detained drugs do not violate the requirement for adequate directions for use established by FFDCA section 502(f)(1) (21 U.S.C. § 352(f)(1)). The law enforcement exemption set forth in 21 C.F.R. § 201.125 exempts the detained drugs from the "adequate directions for use" requirement.[4]

First, the Tentative Decision does not dispute that lethal injection drugs are acquired and used as part of a law enforcement function. The exemption's plain language unambiguously covers lethal injection because that is an aspect of law enforcement. The Tentative Decision therefore acknowledges that, at least "in one sense of" the term, lethal injection is a law enforcement function. Tentative Decision at 11.

Second, the Tentative Decision erroneously construes the exemption's text as limited to law enforcement "not involving clinical use." The text states a list of persons who may receive, purchase, or possess drugs under the exemption. The list is separated by commas that demarcate the differing categories of persons who may receive, purchase, or possess exempt drugs. Some of the descriptions contain the qualifier "not involving clinical use" and others do not. In a series such as this, including the qualifier in some cases and excluding it in others reflects a conscious decision to omit the qualifier where it does not appear.[5]

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[3] This submission and related Attachments contain material that is exempt from disclosure under Freedom of Information Act ("FOIA") exemptions 4, 6 and 7(C). If the agency receives a FOIA request for this submission and/or related Attachments we request the opportunity to object and propose redactions before the material is publicly released.

[4] The Tentative Decision discusses both the prescription drug exemption of 21 C.F.R. § 201.100 and the law enforcement exemption of 21 C.F.R. § 201.125. In section 201.125, the phrase "subject to § 201.100" means a prescription drug as defined in the statute (21 U.S.C. § 353(b)(1)(A)) — not a drug that meets all of the requirements of section 201.100. The exemptions set forth in sections 201.100 and 201.125 are independent of each other. A drug need not comply with one exemption to fit within the other. If a drug needed to meet all of the requirements of section 201.100 to fit within section 201.125, section 201.125 would serve no purpose, because the drug would already be exempt from the requirement for "adequate directions for use."

[5] Under the "rule of the last antecedent," the Tentative Decision is wrong in suggesting that the "not involving clinical use" modifier applies to the categories relating to "pharmacy" and

[redacted]

That conclusion draws support from the original version of the regulation, which addressed both drugs and devices and did not include the law enforcement exemption. 20 Fed. Reg. 9525, 9534 (Dec. 20, 1955). When FDA amended the regulation to add the law enforcement exemption, the agency inserted the new exemption between two others that contained the "not for clinical use" qualifier — but omitted the qualifier from the law enforcement exemption. 21 Fed. Reg. 2326, 2327 (Apr. 11, 1956). That omission reflects a conscious decision not to apply the qualifier to the law enforcement exemption. FDA did not change that decision when it later amended the regulation to separate the device exemption into a different regulation. The operative language of the device law enforcement exemption is identical to the operative language of the drug law enforcement exemption. *Compare* 21 C.F.R. § 801.125 *with* 21 C.F.R. § 201.125.

In the alternative, even if the qualifier could be read into the law enforcement exemption, the detained drugs would fit within the exemption. The plain meaning of the term "clinical use" is use involving medical treatment of a patient. *See, e.g.*, Random House Webster's Unabridged Dictionary (2001) (defining "clinical" as "concerned with or based on actual observation of and treatment of disease in patients rather than experimentation or theory"). The detained drugs are not for a clinical use within the plain meaning of that term.

Third, the Tentative Decision erroneously concludes that the law enforcement exemption is limited to applications that existed, or could have been envisioned by the agency, at the time FDA first promulgated the exemption. Numerous court decisions hold that broadly drafted regulations are not limited to applications that existed, or could have been envisioned by an agency, at the time it promulgated a regulation. *See, e.g.*, *Oregon Paralyzed Veterans of America v. Regal Cinemas*, 339 F.3d 1126, 1133 (9th Cir. 2003). That flexibility is critically important under the FFDCA, where it is often the case that regulations embrace technologies or practices that did not exist at the time the regulations were promulgated. If it were otherwise, the FDA regulatory scheme would be set in stone, unable to adapt to ever-changing developments in critical therapies. Here the broad and general term "law enforcement" easily encompasses law enforcement practices that did not exist at the time FDA first promulgated the exemption.

Furthermore, there is nothing in the contemporaneous regulatory materials from 1956 indicating that FDA intended to limit the scope of the exemption in that manner (or intended to limit the exemption to "controlled buys" or officer training) as asserted in the Tentative

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"chemistry." *See, e.g., Barnhart v. Thomas*, 540 U.S. 20, 26 (2003). But even if that were not the case, the "pharmacy," "chemistry," and "medicine" categories are joined together differently than the law enforcement exemption, which is completely independent of the other categories on the list.

[redacted]

Decision. The Tentative Decision's analysis of the history of law enforcement, including lethal injection and "controlled buys," is an inapplicable post-hoc rationalization that does not control the meaning of a regulation promulgated sixty years ago.

Finally, to the extent that FDA's *actual* contemporaneous statements about the exemption itself are considered — which they need not be — those statements strongly *support* application of the exemption to the detained drugs. At the time FDA promulgated the exemption in 1956, the agency determined that otherwise-applicable "adequate directions for use" requirements "are not necessary for the protection of the public health" when law enforcement is involved. Tentative Decision at 12; 21 Fed. Reg. at 2327. That determination was the essential premise of the exemption, because without the determination there would be no statutory authority to grant the exemption. 21 U.S.C. § 352(f) (conditioning exemptions to section 502(f)(1) on a determination that adequate directions for use are "not necessary for the protection of the public health"). In the 2010/2011 policy statement attached as Exhibit 14 to our October 2015 submission, FDA recognized both that lethal injection is a "law enforcement" function and that the agency has no "public health" justification for restricting distribution or use of lethal injection drugs. FDA's policy statement confirms that the detained drugs fit squarely within the agency's 1956 statements regarding the exemption.

II. The Detained Drugs Do Not Violate Statutory Requirements Governing Adequate Warnings for Users

The detained drugs also do not violate the statutory provision requiring "necessary" and "adequate" warnings for "users" (FFDCA section 502(f)(2) (21 U.S.C. § 352(f)(2))). This provision is unambiguous, and its plain meaning establishes that there is no statutory violation here.

First, the Tentative Decision does not deny the straightforward conclusion that patients are the "users" to be protected by these "necessary" and "adequate" warnings. Even assuming *arguendo* that FDA had authority under section 502(f)(2) to issue such warnings to physicians as well as patients, the patient is the party to be protected by any warnings.[6] The Tentative

[6] The Tentative Decision does not deny that FDA generally relies on section 502(f)(2) to provide warnings directly to patients for purposes of self-administration of non-prescription drugs. The Tentative Decision also does not deny that FDA generally relies on (exemptions from) section 502(f)(1) to provide warnings to physicians for the protection of patients. *See, e.g.*, 21 C.F.R. § 201.100. While the Tentative Decision argues that warnings under section 502(f)(2) may go to physicians rather than directly to patients, the Tentative Decision cites to a Federal Register reference that does not prove the point. Tentative Decision at 14-15. That reference cites generically to section 502(f), which could just as easily be a reference to section 502(f)(1) as a reference to 502(f)(2). The Tentative Decision also cites to a number of regulations, but

[redacted]

Decision does not deny that there are no patient "users" here. Because there are no "users," it is obvious that no warnings are "necessary for the protection of users."[7]

Second, in the alternative, the "law enforcement purpose only" legend is an adequate warning, for the reasons explained in our original submission. The Tentative Decision is not supportable because it does not give any rationale for why that legend allegedly is an inadequate warning.

III. The Detained Drugs Do Not Violate Statutory Provisions Requiring FDA Approval for New Drugs

The detained drugs also do not violate statutory provisions requiring FDA approval for new drugs under FFDCA section 505 (21 U.S.C. § 355). The Tentative Decision does not establish that the detained drugs are "new drugs," because it does not establish that any conditions of use are "prescribed, recommended, or suggested in [their] labeling." 21 U.S.C. § 321(p)(1). As a result, it is not possible to determine whether the detained drugs are generally recognized as

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they do not prove the point either, given that they are incorporated by reference into the prescription drug labeling regulation promulgated as an exemption to section 502(f)(1). *See* 21 C.F.R. § 201.100(d)(3) (citing 21 C.F.R. §§ 210.56, 201.57, 201.80).

[7] Even if FDA were able to support the untenable suggestion that death-row prisoners are "users" within the meaning of the statute, no warnings would be "necessary" to protect them. There certainly is no basis for warnings "against use in those pathological conditions or by children where [a drug's] use may be dangerous to health." No treatment of a pathological condition is at issue here, and children may not receive lethal injection because it is unconstitutional to execute them. *Roper v. Simmons*, 543 U.S. 551 (2005). There also is no basis for warnings addressing the "dosage or methods or duration of administration or application" that are "necessary for the protection of" death-row prisoners. No warnings are "necessary" to "protect" them, because lethal injection carries out a lawfully-imposed capital sentence under which the law requires that a prisoner will not be protected from the consequences of a capital crime. Furthermore, the applicable state statute requires execution through lethal injection. Texas Code Crim. Proc. § 43.14. As the lawful means to implement that requirement, Texas implements execution protocols that tightly control every aspect of the dosage, methods, administration and application of any drug used for lethal injection. *See* Ex. 13. If the protocol is changed to authorize use of thiopental sodium, the same tight restrictions would apply, leaving no purpose for any warning addressing dosage, methods, administration or application. Attachment D. Put another way, even if a warning suggested a dosage, method, administration or application different than the protocol, it would violate state law to deviate from the protocol, rendering the warning meaningless and therefore not "necessary." *Id.* In addition, a warning would not be "necessary" if it simply restated the same dosage, method, administration or application as that required by the protocol.

[redacted]

"safe and effective for use" under those conditions. *Id.*[8] Because FDA has not established that there is a "new drug," 21 U.S.C. § 355 does not require marketing approval.

Determining a drug's "new drug" status based solely on statements in its labeling is a fundamental foundation of FDA's drug approval regime. A drug may be "generally recognized as safe and effective" for some uses but not for others. *See, e.g.*, 21 C.F.R. § 330.1(c)(2). Labeling statements identify the uses for which approval is required (absent general recognition of safety and effectiveness for that use or an exemption from approval requirements). The approval standard accordingly parallels the "new drug" standard. FDA bases approval on adequate and well-controlled investigations of the drug's effectiveness "under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof." 21 U.S.C. § 355(d). When it approves a drug, FDA determines that it is safe and effective "for use under the conditions, prescribed, recommended, or suggested in the proposed labeling thereof." *See* 21 U.S.C. §§ 355(d)(1), (d)(5). Once FDA approves a drug, the agency polices compliance under numerous enforcement provisions specifically tied to statements in labeling. Those provisions include the two misbranding provisions addressed in the Tentative Decision. 21 U.S.C. §§ 352(f)(1), (f)(2).

In stark contrast, determining whether an article is a "drug" in the first place is based on the intended use of the product, which the agency can establish from information outside the labeling. That is because the statute does not limit the "drug" determination to the labeling the way it does for the "new drug" determination. *Compare* 21 U.S.C. § 321(g) *with* 21 U.S.C. § 321(p). FDA therefore has stated that there can be a drug that is not a new drug even though it "would be a new drug if its labeling bore representations for its intended uses." 21 C.F.R. § 201.115. In other words, a drug is not a new drug if the labeling bears no representations for its intended uses.[9]

Based on the foregoing principles, the Tentative Decision is erroneous. *First*, even though the "new drug" determination is limited to statements in the detained drugs' labeling, the Tentative Decision relies primarily on information that is *not* labeling to conclude that they are "new drugs." Tentative Decision at 7. The cited court case and internet articles, and [redacted] prior submission and exhibits, are not labeling, among other things because they are not "upon" the drugs (or their containers or wrappers) and do not "accompany" the drugs. 21 U.S.C.

[8] The Tentative Decision misquotes the statute, omitting the phrase "for use." Tentative Decision at 8.

[9] The "intended use" definition set forth in 21 C.F.R. § 201.128 also extends beyond the labeling. But that definition addresses the scope of exemptions from the "adequate directions for use" requirement and is not relevant to the "new drug" determination.

[redacted]

§ 321(m). Information *outside* of the labeling that documents an intended use for the drugs is not a condition of use "suggested *in* the labeling." The Tentative Decision's analysis therefore conflicts with the plain and unambiguous meaning of the statute.[10]

Second, the deficiencies in the Tentative Decision's statutory construction become clear if one considers its logical extension to the drug approval process. As explained above, the "new drug" definition and the drug approval standard use the identical statutory phrase: "conditions of use prescribed, recommended, or suggested in the labeling" (or "proposed labeling"). If that phrase were stretched to include information outside the labeling, the scope of a new drug approval would extend beyond conditions of use specifically stated in the approved labeling. We are confident that FDA interprets its new drug approvals as limited in scope to conditions of use specifically stated within the four corners of the approved labeling. We also are confident that FDA does not interpret its new drug approvals to authorize additional conditions of use that may be intended — and even possible to document with evidence outside the labeling — if the approved labeling does not expressly state those additional conditions of use. The very same limitation to the four corners of the labeling applies when the agency determines whether a drug is a "new drug" (which will be subject to the integrally related approval requirements).

Third, the Tentative Decision is wrong in claiming that statements in the labeling itself suggest any condition of use. The Tentative Decision is fundamentally deficient because it lists certain statements and simply asserts that they suggest a condition of use (without providing any supporting rationale). Tentative Decision at 6-7. In addition, as a matter of law there is no basis for concluding that the label statements "Thiopental Sodium USP," "Sterile," "Rx only," and "[f]or law enforcement purpose only" suggest conditions of use. As the Tentative Decision acknowledges, thiopental sodium may be used for a variety of different purposes other than lethal injection. Accordingly, the drug's name does not suggest any particular condition of use. There is no basis whatsoever for concluding that the terms "sterile" and "Rx only" suggest any particular condition of use. The "law enforcement purpose only" legend simply invokes a regulatory exemption, and (under our alternative argument) provides a warning not to use the product for any medical purpose, but does not suggest a specific condition of use for which the agency could assess general recognition of safety and effectiveness.

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[10] In 21 U.S.C. § 321(p), the plain meaning of the term "suggested" is "proposed." *See, e.g.*, Random House Webster's Unabridged Dictionary (defining "suggest" as "to mention or introduce (an idea, proposition, plan, etc.) for consideration or possible action"). The Tentative Decision does not argue that the labeling proposes any condition of use. Furthermore, even if a broader definition of the term "suggested" were applied, a condition of use must be suggested "in" the labeling, not outside the labeling, to be a basis for a "new drug" determination.

Fourth, as a matter of law there also is no basis for concluding that a shipping box address sticker (containing [redacted] address) suggests a condition of use in the labeling. Assuming *arguendo* that the address sticker falls within the statutory definition of "labeling,"[11] an address does not suggest a condition of use. Otherwise a drug's condition of use would change every time it was shipped to a new recipient. Furthermore, the specific shipping sticker addressed in the Tentative Decision does not suggest that the drugs will be used for lethal injection simply because they are being sent to [redacted] [redacted] facilities use drugs for many purposes having nothing to do with lethal injection. Numerous drugs are used for medical treatment in infirmaries located in prisons administered by [redacted] Attachment C.

Finally, the Tentative Decision has no basis for concluding that the detained drugs are not generally accepted as safe and effective for any use simply because FDA could not find scientific literature documenting studies with this particular distributor's product. There is no basis for asserting that proof of general acceptance of safety and effectiveness must include scientific studies of a particular manufacturer's or distributor's version of a drug. To the contrary, FDA often establishes general acceptance of safety and effectiveness with respect to active ingredients (whose finished dosage forms have specific required labeling) — and not with respect to finished dosage forms manufactured or distributed by a particular company. *See generally* 21 C.F.R. §§ 331-358.

IV. The "Appearance" Standard of FFDCA Section 801(a) Does Not Change the Foregoing Analysis

The Tentative Decision relies repeatedly on the "appearance" standard of FFDCA section 801(a) (21 U.S.C. § 381(a)) to argue that deference should be given to its regulatory and statutory interpretations. Section 801(a) is referring to a factual or evidentiary determination when it uses the phrase "[i]f it appears from the examination of such samples or otherwise." The court decisions cited in the Tentative Decision address the "appearance" standard in that factual or evidentiary context. In the present matter, the agency is not called on to resolve disputed facts or evidence. Instead, the agency is called on to address pure questions of law presented by the regulations and statutes discussed above. The Tentative Decision erroneously fails to distinguish between factual or evidentiary determinations (addressed by the cited case law) and resolution of the pure questions of law at issue here.

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[11] We contest the proposition that a shipping box address sticker that simply lists the recipient (without more) is labeling at all. There must be "written, printed, or graphic matter" for there to be labeling. The most natural reading of that phrase requires a more substantive statement about a drug than an address where the product will be shipped.

There are well-developed and generally-applicable legal doctrines governing the circumstances under which a court will, and will not, defer to an agency's interpretation of its own governing statute or regulations (and if so what the degree of deference should be). *See, e.g.*, *United States v. Mead Corp.*, 533 U.S. 218 (2001); *Christopher v. SmithKline Beecham Corp.*, 132 S. Ct. 2156 (2012). The case law cited in the Tentative Decision does not hold that the "appearance" language of section 801(a) changes these generally-applicable deference doctrines when FDA interprets statutes and regulations in the context of a decision regarding admissibility of an import. Accordingly, even assuming *arguendo* that that the "appearance" standard could be applied to a pure legal question, there is no basis for asserting that the "appearance" standard establishes a different degree of deference than these generally-applicable doctrines require.

Under these generally-applicable doctrines, there is no basis for deferring to any of the regulatory or statutory interpretations in the Tentative Decision (even assuming the interpretations were the basis for the final decision on the admissibility of the entry). For example, as explained above the language of the law enforcement exemption in 21 C.F.R. § 201.125 is unambiguous, and its plain meaning easily embraces lethal injection.[12] Under these circumstances, the plain meaning of the regulation controls; the case law requiring deference to an agency's interpretation of its own regulations under other circumstances does not require deference here. Other reasons that no deference is due include, but are not limited to, the fact that FDA's regulatory interpretation is a novel one evidently developed in anticipation of litigation, the fact that FDA's interpretation is a post-hoc rationalization, and the fact that the interpretation lacks the formality and precedential effect needed to be properly accorded deference.

The statutory interpretations (of 21 U.S.C. §§ 352(f)(1), 352(f)(2) and 355) also are not entitled to deference under the generally-applicable doctrines described above. If the Tentative Decision is finalized as is and the entry refused, the refusal decision would not be the type of agency action subject to the two-part doctrine announced in *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984). Instead, the refusal decision would only be entitled to "respect according to its persuasiveness." *Mead*, 533 U.S. at 221. And we respectfully submit that the Tentative Decision's statutory interpretations are not persuasive as explained above. Even assuming *arguendo* that the interpretations were subject to a two-part *Chevron* analysis, they should be rejected at *Chevron* step I, because the language of the

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[12] The language of 21 C.F.R. § 201.120 also is unambiguous, and its plain meaning supports [redacted] interpretation. *Compare* October 23, 2015 Submission at 7-8 *with* Tentative Decision at 8 n.5.

[redacted]

statutory provisions is unambiguous, and the interpretations do not square with the plain meaning of those provisions.

V. The Tentative Decision's Statutory and Regulatory Interpretations Conflict With Congressional Intent by Restricting State Options in Implementing Capital Sentences

Congress has made clear that it intends the states to develop their own varying procedures for implementing capital sentences (free of any federal interference). Although a number of different federal statutes allow for capital punishment for specified crimes, Congress has not imposed a uniform federal death sentence protocol. Congress has determined that the federal government "shall supervise implementation of the [capital] sentence in the manner prescribed by the State in which the sentence is imposed." 18 U.S.C. § 3596(a). The congressional deference to state-law procedures is so substantial that a federal capital sentence cannot be imposed at all in a state where the death penalty is illegal under state law; under those circumstances the prisoner must be transferred to a second state, where the federal execution will proceed in accordance with the second state's procedures. *Id.* ("If the law of the State does not provide for implementation of a sentence of death, the court shall designate another State, the law of which does provide for implementation of a sentence of death, and the sentence shall be implemented in the latter State in the manner prescribed by such law.").[13] The current statute requiring deference to state law is a newer version of a substantially similar one that Congress enacted in 1937 (the year before Congress enacted the FFDCA). Act of June 19, 1937, 50 Stat. 304 (originally codified at 18 U.S.C. § 542; recodified at 18 U.S.C. § 3566 (1948); repealed 1984).[14]

The Tentative Decision's statutory and regulatory interpretations conflict with congressional intent by restricting state options in implementing capital sentences. Under those interpretations, it would be unlawful under federal law to use thiopental sodium (from any source) for lethal injection. In other words, those interpretations amount to a federal ban on use of thiopental

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[13] The federal government also may rely on state facilities and personnel to impose the sentence. 18 U.S.C. § 3597(a).

[14] The 1937 statute (50 Stat. 304) provided as follows: "The manner of inflicting the punishment of death shall be the manner prescribed by the laws of the State within which the sentence is imposed. The United States marshal charged with the execution of the sentence may use available State or local facilities and the services of an appropriate State or local official or employ some other person for such purpose, and pay the cost thereof in an amount approved by the Attorney General. If the laws of the State within which sentence is imposed make no provision for the infliction of the penalty of death, then the court shall designate some other State in which such sentence shall be executed in the manner prescribed by the laws thereof."

sodium for lethal injection. A federal ban would conflict with Congress's intent not to interfere with [redacted] discretion to establish and modify its own state-law protocol, which specifically designates the drug or drugs chosen by [redacted] to be used for lethal injection. While [redacted] execution protocol currently does not require use of thiopental sodium, [redacted] considers thiopental sodium to be a contingency should [redacted] find the currently-authorized drug (pentobarbital) unavailable. Ex. 13; Attachment D.[15]

In order to determine congressional intent properly, it is necessary to construe the broad FFDCA provisions at issue (enacted in 1938) together with 50 Stat. 304 (enacted the year before) and 18 U.S.C. § 3596 (enacted in 1994). That is because several statutes addressing the same subject matter should be construed harmoniously if possible. In addition, 50 Stat. 304 provides significant context for the congressional intent underlying the FFDCA provisions at issue, which Congress enacted only one year later; indeed the very same 75th Congress enacted both statutes. Furthermore, construing the FFDCA provisions harmoniously with 18 U.S.C. § 3596 (which is a more specific and later-enacted statute) is fully consistent with the Supreme Court's decision in *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000). In that case, the Court recognized that "'the implications of a statute may be altered by the implications of a later statute,'" that "[t]his is particularly so where the scope of the earlier statute is broad but the subsequent statutes more specifically address the topic at hand," and that "'a specific policy embodied in a later federal statute should control . . . construction of the [earlier] statute, even though it ba[s] not been expressly amended.'" *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 143 (2000) (citations omitted). Construing the FFDCA together with these other

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[15] Congress recodified 50 Stat. 304 most recently at 18 U.S.C. § 3566 (1948). Congress then repealed that statute in 1984. During the ten-year gap before Congress enacted 18 U.S.C. § 3596, the Department of Justice relied on other statutory authority and promulgated regulations governing capital punishment procedures. *See* 28 C.F.R. pt. 26. It appears that these procedures may continue to apply to a limited number of federal crimes outside the scope of 18 U.S.C. § 3596.

These Department of Justice regulations state that unless a court orders otherwise, a capital sentence will be implemented "[b]y intravenous injection of a lethal substance or substances in a quantity sufficient to cause death, such substance or substances to be determined by the Director of the Federal Bureau of Prisons . . . ." 28 C.F.R. § 26.3. Under the authority of these regulations, the Bureau of Prisons has adopted a federal protocol requiring use of thiopental sodium for lethal injection. Current unavailability of thiopental sodium has forced the Bureau of Prisons to consider changing its protocol. Attachment A. An FDA ban on thiopental sodium would conflict with congressional intent in the authorizing statutes for the Department of Justice regulations, because a ban would impinge upon the Bureau of Prisons' discretion to choose which drugs to use for lethal injection (for sentences subject to the regulations).

[redacted]

statutes requires a construction permitting use of thiopental sodium for lethal injection if a state-law procedure authorizes or requires it.[16]

VI. The Tentative Decision's Statutory and Regulatory Interpretations Lead to Absurd Results

The Tentative Decision's statutory and regulatory interpretations also should be rejected because they lead to absurd results. These include the following:

- the conclusion that the statute requires FDA to determine whether the detained drugs are generally recognized as safe and effective for lethal injection, based on any "adequate and well-controlled clinical trials evaluating [the distributor's] thiopental sodium for use as part of a lethal injection that have been published in the scientific literature." Tentative Decision at 6, 8.

- the conclusion that lethal injection drugs require adequate directions for lay users of the drugs — and do not fall within an exemption to that requirement that applies when such directions are not necessary for the protection of the public health — because lethal injection constitutes a "clinical use" of a drug. Tentative Decision at 9, 13.

- the conclusion that lethal injection drugs must include warnings where their "use may be dangerous to health," or where there are "unsafe dosage or methods or duration of administration or application." Tentative Decision at 14.

Conclusions as outlandish as these signify that the Tentative Decision's interpretations do not reflect congressional intent. *Cf. Heckler v. Chaney*, 470 U.S. 821, 827 (1985) (referring to "the implausible result that the FDA is required to exercise its enforcement power to ensure that States only use drugs that are 'safe and effective' for human execution."). It is well established that a statutory interpretation that leads to absurd results must be rejected. *See, e.g., Pub. Citizen v. U.S. Dep't of Justice*, 491 U.S. 440, 454-55 (1989).

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16 The Supreme Court's decision in *Brown & Williamson* applies with particular force to the Tentative Decision's interpretation of the term "new drug." In *Brown & Williamson*, the Supreme Court reviewed an FDA interpretation of the "device" definition that would result in a ban of cigarettes. Even though nicotine fit within the literal definition of the term "drug" (*see* 529 U.S. at 162), the Supreme Court held that cigarettes are not drug delivery "devices," because if they were they would necessarily be banned as unsafe. Banning cigarettes would conflict with the congressional intent expressed in subsequent statutes permitting tobacco use. 529 U.S. at 143-44. Similarly, in the present matter, interpreting the term "new drug" to apply to the detained thiopental sodium would result in a ban of that drug for lethal injection purposes, contrary to the congressional intent (expressed in the other statutes precluding federal interference with state-law execution procedures).

VII. FDA Has Enforcement Discretion to Admit the Detained Drugs Even if it Were to Conclude That the Drugs Violate the Statute

FDA has enforcement discretion to admit the detained drugs into domestic commerce even if it were to conclude that the drugs violate the statute. In connection with that issue, the Tentative Decision cites to the District Court's decision in *Beaty v. FDA*, 853 F. Supp. 2d 30 (D.D.C. 2012) and the D.C. Circuit's decision in the same case (*Cook v. FDA*, 733 F.3d 1 (D.C. Cir. 2013)). We respectfully submit that *Beaty/Cook* does not control the agency's disposition of the detained drugs.

First, *Beaty/Cook* is distinguishable. The parties in that case stipulated that the drugs at issue were unapproved new drugs that violated FFDCA section 505(a). *See Beaty*, 853 F. Supp. 2d at 34 n.2. In addition, the facts underlying the stipulation are entirely different than those presented here. The *Beaty/Cook* drugs contained labeling stating specific medical uses (concerning general anesthesia, convulsions and intracranial pressure). *See* Attachment B (Griffin Decl. Ex. 19 at 5-8). The parties evidently agreed that there was no general acceptance of safety and effectiveness for the uses stated in the labeling. And there was no FDA approval for the uses stated in the labeling.

The only other violations addressed by *Beaty/Cook* are misbranding violations unrelated to FFDCA section 502(f)(1) or 502(f)(2). The *Beaty/Cook* parties again stipulated to these violations (which were failure to list the drugs under FFDCA section 502(o) and failure to include an "Rx only" label legend under FFDCA section 503(b)(4)(A)). *See Beaty*, 853 F. Supp. 2d at 34 n.2; *Cook*, 733 F.3d at 3. These violations are irrelevant here. As established in our original submission and exhibits, the detained drugs were properly listed, and an "Rx only" legend does appear on the label.

Second, we respectfully submit that *Beaty* and *Cook* are wrongly decided with respect to their rulings depriving the agency of discretion to make a particularized decision admitting into domestic commerce, rather than refusing, a specific entry of violative imported drugs. FDA does have enforcement discretion to admit the specific entry of detained drugs at issue here even if it were to conclude that they violate the statute. In that regard, we incorporate by reference the arguments in the portions of the government's D.C. Circuit briefs in *Cook* that address or support FDA discretion to make particular import admissibility decisions about specific entries (to the extent that those arguments are not inconsistent with [redacted] arguments in this matter).

We recognize that FDA currently feels compelled to respect the *Beaty/Cook* decision regarding enforcement discretion, and we present these arguments here to preserve them for possible later judicial resolution if necessary. [redacted] is not precluded from relitigating the enforcement discretion issue because it was not a party in *Beaty/Cook*. While FDA was a party

[redacted]

in *Beaty/Cook*, the agency may relitigate the enforcement discretion issue with a different party in a different Circuit. *See, e.g., United States v. Mendoza*, 464 U.S. 154, 160-62 (1984) (rejecting application of nonmutual collateral estoppel against the government); *Johnson v. U.S. R.R. Retirement Bd.*, 969 F.2d 1082, 1093 (D.C. Cir. 1992) (describing doctrine of intercircuit non-acquiescence).

* * *

We therefore request FDA to make a final decision to release the detained drugs and instruct Customs and Border Protection to implement that decision by lifting that agency's detention, to permit immediate delivery to [redacted] If FDA makes a final decision refusing admission of the detained drugs, [redacted] requests the agency to retain custody of the drugs under conditions that protect against any degradation to the quality, potency, identity or efficacy of the drugs pending completion of any judicial review of the refusal action. Alternatively, if FDA were to refuse the entry but deny the request to retain custody, [redacted] invokes its statutory right to be given a minimum of 90 days to export the drugs to the original foreign distributor (who would hold them ready for re-importation if a court were to rule that their admission into domestic commerce is lawful). *See* 21 U.S.C. § 381(a); Attachment E.

If you have any questions regarding the discussion set forth above, please do not hesitate to contact me at [redacted] or [redacted].

Sincerely,

[redacted]

cc: Capt. Domenic Veneziano, Director, Division of Import Operations, FDA
Douglas Stearn, Director, Office of Enforcement and Imports, FDA
[redacted], Co-Counsel to TDCJ

[redacted]

Enclosures:

Attachment A: Documents Pertaining to Federal Execution Protocol

Attachment B: Labeling for *Beaty/Cook* Drugs

Attachment C: Affidavit of [redacted]

Attachment D: Affidavit of [redacted]

Attachment E: Affidavit of [redacted]

[redacted]

ATTACHMENT A

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

JAMES ROANE, JR., et al.,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	**Civil Action No. 05-2337(RWR/DAR)**
	)	
ERIC H. HOLDER, JR., et al.,	)	
	)	
Defendants.	)	
	)	

THE PARTIES' JOINT MOTION FOR AN ORDER ESTABLISHING A DEADLINE FOR DEFENDANTS TO SUPPLEMENT DISCOVERY, IF APPROPRIATE, AND TO EXTEND PLAINTIFFS' DEADLINE FOR FILING MOTION TO REOPEN DISCOVERY

For the reasons stated herein, Plaintiffs and Defendants jointly and respectfully move the Court for an Order establishing a deadline for Defendants to supplement their discovery responses, if determined appropriate, and extending Plaintiffs' deadline for filing a motion to reopen discovery, as stated herein. Good cause exists to grant this motion:

1. On April 14, 2011, Plaintiffs advised the Court that Defendants had publicly announced that they "do[] not have any reserves of sodium thiopental for lethal injections." Since sodium thiopental is one of the chemicals specified by the Defendants' lethal injection protocol, Plaintiffs' noted that this circumstance may require the Defendants to modify the protocol, which in turn may require additional discovery.

2. On April 14, 2011, the Court ordered (a) that the parties meet and confer regarding the need for Defendants to supplement discovery, and the need to reopen discovery; (b) that the parties jointly file a status report on this subject by April 29, 2011; and (c) that Plaintiffs file, by no later than May 13, 2011, a motion to reopen discovery.

3. On May 3, 2011, after considering the Parties' Joint Status Report Regarding Supplementation of Discovery (Doc. 281), this Court ordered that Defendants supplement their discovery responses by no later than May 9, 2011.

4. On May 9, 2011, Defendants filed an unopposed request to extend the time to complete their supplementation of discovery as ordered by the Court until May 16, 2011 (Doc. 283). Plaintiffs agreed to that extension on the condition that Defendants would agree to an extension of time for Plaintiffs to file a motion to reopen discovery until May 27, 2011. Defendants so agreed. On May 9, 2011 and May 16, 2011, Defendants produced supplemental responses to Plaintiffs' written discovery requests, based on the current lethal injection protocol. Defendants' position is that they have complied with the Court's May 3, 2011 Order based on the current protocol but that, as explained below, they might have to supplement their discovery depending on whether the Bureau of Prisons modifies the lethal injection protocol.

5. On May 13, 2011, counsel for Defendants wrote to counsel for Plaintiffs, stating that, "[t]he Federal Bureau of Prisons is currently considering a revision to its lethal injection protocol;" and is "likely" to make a final determination "by this summer" as to whether to modify the protocol. Counsel for Defendants therefore proposed that the parties move for a continuance of the schedule for briefing the issue of additional discovery "until the Bureau makes its determination but no later than July 29, 2011." Defendants also recommended that the parties postpone two of the remaining three depositions of Plaintiffs' experts until the Bureau decides whether, and if so, how to modify the lethal injection protocol. The parties subsequently agreed to postpone the remaining three depositions until the Bureau of Prisons makes its determination regarding the lethal injection protocol.

6. The parties cannot determine what, if any, additional discovery may be required, until the Bureau of Prisons determines whether to modify its protocol and, if it does decide to modify the protocol, until the protocol is so modified.

For the foregoing reasons, the parties jointly and respectfully request that the Court issue an order providing that Defendants shall supplement their discovery responses by July 29, 2011, if appropriate, and extending until August 26, 2011, the deadline for Plaintiffs to make any motion for additional discovery. In the event that Defendants have not made a decision by July 29, 2011, as to whether to modify the protocol, the parties will meet and confer prior to that date, and submit a joint status report to the Court on or before that date.

Respectfully submitted,

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